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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,082	02/28/2002	Wolfgang Dietmaier	18668-US1	3192

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/087,082	<b>Applicant(s)</b> DIETMAIER ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Applicants' response to the office action filed on October 25, 2004 has been entered and considered.
2. The instant application filed on February 28, 2002 is a continuation of US nonprovisional application 09/270,933 filed on 3/16/1999, which claims benefit of a foreign application Germany 198 13 317.0 filed on 3/26/1998.
3. Claims 1,3-17 are pending.

**Response to arguments**

4. Applicants' response to the office action is fully considered and found not persuasive.
5. The following is the rejection made in the previous office action under 35 USC 103(a):

Claims 1, 3-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggeling et al. (Hum Genet., Vol. 99, pages 266-270, 1997) in view of Ando et al. (J Clin Microbiol., Vol. 35, No.3, pages 570-577, 1997).

Eggeling et al. teach a method for the amplification of nucleic acid fragments from a sample said method comprises first (primer extension pre amplification) and second (specific amplification), wherein said first amplification is carried out using completely randomized primers (see page 267, column 1, paragraph 3 of metrials and methods section) and said second amplification reaction is carried out using specific primers (see page 267, column 1, paragraph 4). Eggeling et al. also teach that (i) said sample comprises cells (blood cells) (see page 267, column 1, paragraph 1 under materials and methods); (ii) treating sample of cells with proteinase K (see page 267, column 1, paragraph 2 under materials and methods section); primer extension temperature in the first amplification is carried out at increased temperature at least

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some of the successive amplification cycles (see page 267, column 1, paragraph 3 of materials and methods section); However, Eggeling et al. did not teach use of a mixture of at least two DNA polymerases.

Ando et al. teach a method for the amplification of nucleic acid fragments from a sample (see page 571, column 2, paragraphs 1-3), said method comprises first (reverse transcription) and second (PCR) amplification reactions (see page 571, column 2, paragraph 3, page 573, Fig. 1), and said first and second amplification reactions were carried out using the same mixture of at least two DNA polymerases, at least one of which possesses 3'-5' exonuclease activity (see page 572, column 1, lines 1-17). Ando et al. teach that (i) said mixture of DNA polymerases comprises a DNA polymerase without 3'-5' exonuclease activity (Taq DNA polymerase) and a DNA polymerase with 3'-5' exonuclease activity (pwo DNA polymerase) (see page 572, column 1, lines 1-17, page 576, column 2, lines 5-13);(ii) that the sample comprises a pool of cDNAs (see page 571, column 1, paragraph 1, column 2, paragraph 1, page 575, column 1, paragraph 4); sample comprises stool specimen, which comprise various viral cells (see page 571, column 1, paragraph 1, column 2, paragraph 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method for amplification of nucleic acid fragments as taught by Eggeling et al. with the method of amplification of nucleic acids using a mixture of DNA polymerases having high processivity as taught by Ando et al. to achieve expected benefit of developing an improved method of amplification because Ando et al. taught the use of the combination of DNA polymerases would amplify a long templates (see page 573, column 2, lines 9-10, page 575, column 1, lines 1-15, column 2, paragraph 2). An ordinary practitioner

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would have been motivated to combine the method of amplification of a nucleic acid as taught by Eggeling et al. with the step of adding a mixture of at least two DNA in order to achieve the expected advantage of developing a high sensitive amplification of long templates of nucleic acid molecules.

***Response to the Arguments:***

With regard to the above rejection, Applicants' arguments are fully considered and found not persuasive. Applicants' argue that the instant claims are not obvious over Eggeling in view of Ando et al. since the instant invention is drawn to amplify nucleic acid fragments having a length between 100 and 1000 base pairs as disclosed in the instant specification. Applicants further argue that the disclosure of Ando et al. teaches a method for amplifying long templates ranging a 3-kilobase region and would not provide any motivation to use a mixture of DNA polymerases to amplify a nucleic acid fragment having a length between 100 and 1000 base pairs. Applicants' arguments are fully considered and found not persuasive because the limitation that "amplifying a nucleic acid fragment having a length between 100 and 1000 base pairs" is *not* present in the instant claims. As stated in MPEP 2145, "Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims". In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993), the instant independent claims do not recite this limitation and specification is not be read into the claims. Thus the limitations upon which Applicants' arguments are relied upon, are not in the claims and thus the instant claims do not exclude the inclusion of amplifying longer templates as taught by Ando et al. Thus an ordinary skill in the art would have had a reasonable expectation of success to combine the method as taught by Eggeling et al. with a mixture of DNA polymerases as taught by Ando et al. for the

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purpose of achieving an expected advantage of developing a sensitive and improved method for amplifying nucleic acid fragments.

Applicants also argue that the claimed invention provides surprising improvements to the preamplification methods known on the prior art, as disclosed in the specification, and assert that these surprising results show that the use of a mixture of at least two DNA polymerases as taught by Ando et al. would not be obvious to combine with preamplification method as taught by Eggeling. Applicants' arguments are fully considered, however, the arguments are not persuasive. As noted in MPEP 716.02 (d) which states "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens , 622 F.2d 1029, 206 USPQ 289, 296 (CCPA 1980)". Here, no showing of the unexpected result or a declaration is provided to show the surprising improvements over the known prior art. Therefore the rejection is maintained herein.

### ***Conclusion***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after


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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
December 27, 2004

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
1/5/05